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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

----x **ECF CASE** 

ASSOCIATION FOR MOLECULAR

PATHOLOGY, et al.,

09 Civ. 4515 (RWS)

Plaintiffs,

**DEFENDANT UNITED STATES** v.

PATENT AND TRADEMARK

**OFFICE'S RESPONSE TO** 

UNITED STATES PATENT AND TRADEMARK PLAINTIFF'S LOCAL CIVIL

OFFICE, et al., **RULE 56.1 STATEMENT** 

Defendants.

Pursuant to Rule 56.1(b) of the Local Civil Rules of the United States District Court for the Southern District of New York, defendant United States Patent and Trademark Office ("USPTO"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, hereby responds to plaintiffs' Local Civil Rule 56.1 Statement of Material Facts as follows, without admitting that any of plaintiffs' statements are material:

- 1 20. Denies knowledge or information sufficient to form a belief as to the truth of the statements asserted in paragraphs 1-20, which allege facts concerning the various plaintiffs.
- 21 39. Denies knowledge or information sufficient to form a belief as to the truth of the statements concerning the identity of the experts in paragraphs 21-39. Plaintiffs'

statements that the individuals identified in those paragraphs are experts is a legal conclusion that is not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).<sup>1</sup>

- 40. The statements in paragraph 40 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that genes and their sequences as they are found in their native chromosomes are naturally-occurring. The remaining statements in paragraph 40 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 41. The statements in paragraph 41 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that genes are the basic units of heredity in living organisms; that a gene is a segment of DNA; and that genes encode mRNAs, which serve as instructions for the amino acid sequence of proteins during translation. Disputes that DNA is the molecule that makes life possible, as many types of molecules are found in cells and necessary for cell functioning. (See Bruce Alberts, et al., Molecular Biology of the Cell (3d Ed. 1994) ("Alberts") at 4-8, 41-60). Disputes that DNA encodes the instructions for the development and functioning

<sup>&</sup>lt;sup>1</sup> Many paragraphs in plaintiffs' 56.1 Statement include legal conclusions and/or characterizations of plaintiffs' claims, as well as assertions of fact immaterial to plaintiffs' two purported constitutional claims against the USPTO. Accordingly, the USPTO has no obligation to respond to such matters, and by not responding the USPTO does not admit them. See L. Civ. R. 56.1(a); The American Med. Ass'n v. United Healthcare Corp., 00 Civ. 2800 (LMM), 2007 WL 1771498, \*2 (S.D.N.Y. June 18, 2009) (When parties . . . file Rule 56.1 Statements . . . [that] lack citations or are in some other way deficient, courts are 'free to disregard' the assertions therein.") (quoting *Holtz v. Rockefeller & Co, Inc.*, 258 F.3d 62, 73 (2d Cir. 2001)).

of cells, as many molecules as well as external forces affect cell development and functioning. (Id. at 721-87, 1037-66). The remaining statements in paragraph 41 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement.

See L. Civ. R. 56.1(a).

- 42. The statements in paragraph 42 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Disputes the statements in paragraph 42. Normal diploid human cells have 23 pairs (or 46 total) chromosomes, 22 pairs of which are autosomal chromosomes, and 1 pair of which is sex chromosomes. (See Alberts at 356).
- 43. The statements in paragraph 43 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that Watson and Crick identified the structure of DNA in 1953. The remaining statements in paragraph 43 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 44. The statements in paragraph 44 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that the genetic codes consists of four nucleotide bases which may be represented by U, C, A, and G in RNA (and T, C, A, and G in DNA). Does not dispute that triplets of these bases, called "codons," which correspond to one of the twenty amino acids found in proteins. (See Alberts at 230-32). The remaining statements in paragraph 44 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 45. The statements in paragraph 45 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that, during transcription, a strand of DNA is used as a template to construct an mRNA. Does not dispute that non-coding regions of RNA called "introns" are removed from the mRNA during normal RNA-processing, resulting in an mRNA consisting primarily only of protein-coding regions of RNA called "exons." Does not dispute that, during translation, mRNA is used by ribosomes as a blueprint for constructing the primary structure of proteins. Does not dispute that the ribosomes "read" nucleotide triplets in mRNA, called "codons," to construct the primary structure of proteins, or that each codon corresponds to one of the twenty amino acids. The remaining statements in paragraph 45 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 46. The statements in paragraph 46 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that the genome is contained within most cells in the body. Does not dispute that the genome is responsible for many phenotypic traits, including sex and eye color. Denies sufficient knowledge or information sufficient to form a belief as to the truth of the remaining statements in paragraph 46.
- 47. The statements in paragraph 47 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that a gene is a region of DNA that controls a discrete hereditary characteristic, usually corresponding to a single protein or RNA; and includes the

entire functional unit, encompassing coding DNA sequences, non-coding regulatory DNA sequences, and introns. (See Alberts at G-10). Does not dispute that a gene sequence is the sequence of nucleotide bases in a specific region of the genome. The remaining statements in paragraph 47 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 48-50. The statements in paragraphs 48-50 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. <u>See</u> L. Civ. R. 56.1(a).
- 51. The statements in paragraph 51 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that, excluding identical siblings, no two humans are genetically the same. Denies sufficient knowledge or information sufficient to form a belief as to the truth of the remaining statements in paragraph 51.
- 52. The statements in paragraph 52 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that small scale variation can occur, manifested as slight sequence difference between the same genes in different individuals. Does not dispute that these differences may involve the deletion, insertion or inversion of nucleotide pairs. The remaining statements in paragraph 52 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 53. The statements in paragraph 53 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L.

- Civ. R. 56.1(a). Does not dispute that large scale variation can occur in the genome, and may involve the deletion, insertion, replication or inversion of several hundred nucleotide pairs. The remaining statements in paragraph 53 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 54. The statements in paragraph 54 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that mutations are inheritable changes in the nucleotide sequence of the chromosome. Does not dispute that mutations may be neutral, beneficial or harmful. Does not dispute that mutations include deletions, insertion or inversion of nucleotide pairs. The remaining statements in paragraph 54 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 55. The statements in paragraph 55 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that "DNA sequencing" is the process by which the nucleotide sequence of an isolated DNA may be determined. DNA sequencing is performed on isolated DNA using one of two in vitro chemical techniques: the Maxim-Gilbert chemical enzymatic method and the Sanger method. (See Alberts at 292, 296-98). The remaining statements in paragraph 55 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 56. The statements in paragraph 56 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute the statements set forth in paragraph 56.

- 57. The statements in paragraph 57 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the statements asserted in paragraph 57.
- 58. The statements in paragraph 58 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. <u>See</u> L. Civ. R. 56.1(a).
- 59. Does not dispute that, assuming no laboratory error, the sequence of a gene as it is found in its native chromosome is not altered when isolated and sequenced in a laboratory. The remaining statements in paragraph 59 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 60. The statements in paragraph 60 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 61. The statements in paragraph 61 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that complementary DNA, or "cDNA," is produced by the reverse transcription of mRNA to form a double-stranded, complementary DNA molecule. Does not dispute that cDNA, like the mRNA from which it was derived, lacks non-coding regions of nucleotides, called "introns." Does not dispute that cDNA may by sequenced. Does not dispute that a cDNA may be transcribed to produce an mRNA that is identical to the fully-processed

mRNA from which it was originally derived. Does not dispute that in DNA and RNA cytosine (C) binds to guanosine (G), that in DNA adenosine (A) binds to thymidine (T), and that in RNA adenosine (A) binds to uracil (U). The remaining statements in paragraph 61 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 62. The statements in paragraph 62 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that complementary DNA, or "cDNA," is produced in vitro by the reverse transcription of mRNA to form a double-stranded, complementary DNA molecule. Does not dispute that cDNA, like the mRNA from which it was derived lacks non-coding regions of nucleotides, called "introns." Does not dispute that cDNA may by sequenced. Does not dispute that a cDNA may be transcribed to produce an mRNA that is identical to the fully-processed mRNA from which it was originally derived. The remaining statements in paragraph 62 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 63. The statements in paragraph 63 are characterizations of plaintiffs' claims and immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
  - 64. Does not dispute the statements in paragraph 64.
- 65. The statements in paragraph 65 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Disputes the statements in paragraph 65. For example, "an isolated gene can be altered

(engineered) at will and transferred back into cells in culture. With more difficulty, the redesigned gene can be inserted into the germ line of an animal or plant, so as to become a functional and heritable part of that organism's genome." (Alberts at 291).

- 66. The statements in paragraph 66 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that gene sequencing may be used in diagnostic testing, and that the resultant sequence data may be examined to determine if it contains any alterations or mutations associated with a particular condition.
- 67. The statements in paragraph 67 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that scientists often refer to a gene without mutations as the "wild type" or "normal" gene. The remaining statements in paragraph 67 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement.

  See L. Civ. R. 56.1(a).
- 68. The statements in paragraph 68 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that mutations in genes can occur in nature without the aid of man. The remaining statements in paragraph 68 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 69. The statements in paragraph 69 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the

statements in paragraph 69 because the USPTO is unaware of what is meant by the term "full sequencing."

- 70. The statements in paragraph 70 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 70 because the USPTO is unaware of what is meant by the term "full sequencing."
- 71. The statements in paragraph 71 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that genetic mutations may be investigated to determine if they are associated with a particular disease. The remaining statements in paragraph 71 are characterizations of plaintiffs' claims and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 72-73. The statements in paragraphs 72 and 73 are characterizations of plaintiffs' claims and immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. <u>See</u> L. Civ. R. 56.1(a).
- 74-75. The statements in paragraph 74 and 75 are characterizations of plaintiffs' claims and immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraphs 74-75.

76. The statements in paragraph 76 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute the statements in paragraph 76.

77-80. The statements in paragraphs 77-80 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement.

See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraphs 77-80.

81-82. The statements in paragraphs 81 and 82 are characterizations of plaintiffs' claims and are immaterial to plaintiffs' claims against the USPTO, and therefore are not statements appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 83. The statements in paragraph 83 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that BRCA 1/2 genetic testing can be an important factor in structuring an appropriate course of cancer treatment. The USPTO denies knowledge or information sufficient to form a belief as to the truth of the remaining statements in paragraph 83.
- 84. The statements in paragraph 84 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 84.
- 85. The statements in paragraph 85 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute the statements in paragraph 85.

- 86. Does not dispute the USPTO issued the patents listed in paragraph 86. The remainder of the statements in paragraph 86 are characterizations of plaintiffs' claims and not statements appropriately included in a Local Civil Rule 56.1 Statement. *See* L. Civ. R. 56.1(a).
- 87. Plaintiffs' statement in paragraph 87 is a legal conclusion and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). The USPTO respectfully refers the Court to the cited statute for its full and complete terms.
- 88. The statements in paragraph 88 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 89. The statements in paragraph 89 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 90. The statements in paragraph 90 are vague and/or not statements of fact, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 91. The statements in paragraph 91 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the

USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 92. The statements in paragraph 92 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 93. The statements in paragraph 93 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that BRCA1 and BRCA2 genes are naturally occurring. The remainder of the statements in paragraph 93 are characterizations of plaintiffs' claims and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 94. The statements in paragraph 94 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 95. The statements in paragraph 95 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 96. The statements in paragraph 96 are legal conclusions and/or characterizations of plaintiffs' claims, and are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 97. The statements in paragraph 97 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 98. Denies knowledge or information sufficient to form a belief as to the truth of the statements in the second and third sentences of paragraph 98. The remainder of the statements in paragraph 98 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 99. The statements in paragraph 99 are immaterial to plaintiffs' claims against the USPTO and not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). Does not dispute that BRCA1 and BRCA2 genes are naturally occurring. The remainder of the statements in paragraph 99 are characterizations of plaintiffs' claims and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 100. The statements in paragraph 100 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 101. The statements in paragraph 101 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 102. Denies knowledge or information sufficient to form a belief as to the truth of the statements in the last sentence of paragraph 102 because the word "sequence" is vague as used. The remaining statements in paragraph 102 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 103-108. The statements in paragraphs 104-108 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 109. The statements in paragraph 109 are vague in terms of the use of the word "control," and/or are legal conclusions or characterizations of plaintiffs' claims, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 110-112. The statements in paragraphs 110-112 are vague, legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- patents are being referenced. The remainder of the statements in paragraph 113 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a). The USPTO further respectfully refers the Court to the cited USPTO Guidelines for their full and complete terms.
- 114. Disputes that DNA and genes are not chemicals. (Alberts at 46-47, 58-60). The statements contained in the remainder of paragraph 114 are are legal conclusions and/or characterizations of plaintiffs' claims, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 115-123. The statements in paragraphs 115-123 are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 124. The statements in paragraph 124 are vague, not statements of fact, and/or legal conclusions, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 125-138. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraphs 125 through 138, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 139. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 139, and states that those statements are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 140. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 140, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 141. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 141, and states that those statements are legal conclusions and/or characterizations of plaintiffs' claims, and are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 142-175. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraphs 142 through 175, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 176. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 176 to the extent they are vague, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

- 177. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 177, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 178. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 178 to the extent they are vague, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 179. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraph 179, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 180. States that the statement in paragraph 180 is not a statement appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).
- 181-210. Denies knowledge or information sufficient to form a belief as to the truth of the statements in paragraphs 181 through 210, and states that those statements are immaterial to plaintiffs' claims against the USPTO, and therefore are not matter appropriately included in a Local Civil Rule 56.1 Statement. See L. Civ. R. 56.1(a).

By submitting this response, the USPTO does not waive its right to contend that any of the above-referenced facts are not material to this action.

Dated: New York, New York December 24, 2009

> PREET BHARARA United States Attorney for the Southern District of New York Attorney for Defendants

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